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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/090,326	03/04/2002	Tony E. Godfrey	010211	5534

26285 7590 12/24/2003

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535 SMITHFIELD STREET  
PITTSBURGH, PA 15222

EXAMINER
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WILDER, CYNTHIA B

ART UNIT	PAPER NUMBER
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1637

10

DATE MAILED: 12/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/090,326

Applicant(s)

GODFREY ET AL.

Examiner

Cynthia B. Wilder, Ph.D.

Art Unit

1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 25 June 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-53, 59-67 and 77-104 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-53, 59-67 and 77-104 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

Art Unit: 1637

**DETAILED ACTION**

1. The prior Office Action submitted 9/3/2003 concerning the restriction requirement is being withdrawn per Applicant's request to address claims not canceled in the preliminary amendment of June 25, 2003. The restriction requirement of 6/17/2003 and 9/3/2003 are being combined to address all claims. It is noted that claims 54-58 and 68-76 have been canceled. Claims 1-53, 59-67 and 77-104 are pending.

***Election/Restriction***

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:
- I. Claims 1-53, 59-66, 78-86, drawn to a PCR method, classified in class 435, subclass 91.1.
  - II. Claims 67, 87-104 drawn to oligonucleotides and kit, classified in class 536, subclass 24.33 and class 435, subclass 810.
  - III. Claims 77, drawn to a diagnostic method, classified in claim 435, subclass 6.

***Sequence Election Requirement Applicable to Groups I and II***

3. In addition, Groups I and II detailed above reads on patentably distinct SEQ ID Number sets. Each of the sequences or set of sequences are patentably distinct because the sequences are structurally unrelated sequences and a further restriction is applied to the Groups listed above. Applicant must further elect a first primer set (2 sequences) and a second primer set (2 sequences) comprising 4 SEQ ID numbers selected from SEQ ID NOS: 3, 4, 6, 7, 11, 12, 13, 14, 16, 17, 19 and 20 to be examined along with the elected group.

Art Unit: 1637

**Applicant is advised that examination will be restricted to only the elected 4 sequences (SEQ ID NOS) consisting of the first and second primer sets along with the corresponding elected Group.**

**Applicant is also advised that this election should not be construed as a species election.**

4. The inventions are distinct, each from the other because of the following reasons:

Inventions I, III and II are related process of use and product. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the oligonucleotide and cartridge comprising primers of invention II can be used in a materially different process such as in mini-sequencing assays to detect a polymorphic variant in a sample or in methods of mutagenesis or in methods of nucleic acid cloning.

5. Inventions I and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different starting reagents, different method steps leading to different objectives. For example, the PCR method comprising multiplex PCR and TR-PCR of Invention I can function methods of amplification to detect or classify microorganism or viral species. The method can also be used in purification procedures or in methods of detecting chromosomal imbalance whereas the method of invention III is drawn to a diagnostic method for detecting

metastasized adenocarcinoma of the esophagus using method steps to determine expression of an indicator transcript as compared to a threshold level. The searches of the different inventions are not coextensive because diagnostic methods are not necessarily combined with or required for the function of PCR methods. The different inventions are patentably distinct requiring different fields of search.

6. Because these inventions are distinct for the reasons given above and the search required for any one Group is not required for any other Group, restriction for examination purposes as indicated is proper.

7. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventor ship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventor ship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

9. In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim

Art Unit: 1637

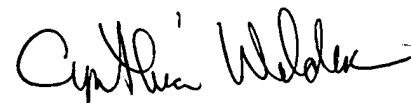
will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. 103(b)", 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP 804.01.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia B. Wilder, Ph.D. whose telephone number is (703) 305-1680. After January 14, 2004, the examiner can be reached at (571) 272-0791. The examiner works a flexible schedule and can be reached by phone and voice mail. Alternatively, a request for a return telephone call may be emailed to [cynthia.wilder@uspto.gov](mailto:cynthia.wilder@uspto.gov). Since email communications may not be secure, it is suggested that information in such request be limited to name, phone number, and the best time to return the call

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (703) 308-1119. The official fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308 0196.

  
CYNTHIA WILDER  
PATENT EXAMINER  
AU 1637